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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,798	11/26/2003	Ajit Lalvani	117-485	6314

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,798

Applicant(s)

LALVANI ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,14,16-18 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-12,14,16-18,28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



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DETAILED ACTION

1. Applicants' Response to Office Action, received 22 July 2005, is acknowledged. Claims 1, 3-7, 14, 16, and 18 have been amended. New claims 28-30 have been added.
2. 1, 3-12, 14, 16-18, and 28-30 are pending and under consideration.

Rejections/Objections Withdrawn

3. The objection to claim 1 is withdrawn in light of the amendment of the claim.
4. The objection to claim 7 is withdrawn in light of the amendment of the claim.
5. The objection to claim 14 is withdrawn in light of the amendment of the claim.
6. The objection to claim 18 is withdrawn in light of the amendment of the claim.
7. The rejection of claims 1, 3-12, 14 and 16-18 under 35 U.S.C. 112, second paragraph, indefiniteness for peptides represented by, is withdrawn in light of the amendments of the claims.

Rejection Maintained

8. The rejection of claim 14 under 35 U.S.C. 102(e) as being anticipated by Andersen et al (U.S. Pat. No. 5,955,077) is maintained for the reasons of record.

Applicants argue that Andersen et al do not disclose a composition comprising SEQ ID NO:14. There is no recited SEQ ID NO:14 in applicants' claim 14.

The examiner apologizes for the typographical error in the rejection. The rejection was to recite SEQ ID NO:4.

The examiner has considered applicants' argument concerning the lack of Andersen et al to disclose a composition comprising applicants' sequence, but does not find it persuasive.

The rejected claim, as newly amended, is drawn to "A kit comprising one or more peptides selected from the group consisting of peptides of SEQ ID NOS:3, 4, 7, 8, 9, 10, 11 and

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12." Recitation in the claim of "for carrying out a method according to claim 1" is merely an intended use and thus does not place any patentability restriction on the product. Likewise, the rest of the claim is directed to peptides which are "optional", thus, one of the embodiments of claim 14 is "A kit comprising one or more peptides selected from the peptides represented by SEQ ID Nos:3, 4, 7, 8, 9, 10, 11 or 12."

Since only one element is required to fulfill the claimed invention, i.e., one peptide represented by SEQ ID NO:4, Andersen et al do teach the claimed invention because they teach a peptide comprising a ≥ 12 amino acid subsequence of the amino acid sequence of SEQ ID NO:2 (claim 26).

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3-12, 14, 16-18, and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 1 now recites "optionally, one or two further peptides of SEQ ID NOS: 1 and/or 2". It is unclear if the additional peptide(s) are to be the entire sequence of SEQ ID NO:1 or 2 or subsequences of said SEQ ID NO:1 or 2.

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Newly amended claim 3 now recites "comprising the peptides of SEQ ID NOS: 1, 2, 3, 4, 8, 9 and 10". It is unclear if the additional peptide(s) are to be the entire sequence of SEQ ID NO:1, 2, 3, 4, 8, 9 and 10, or subsequences of said SEQ ID NO:1, 2, 3, 4, 8, 9, and 10.

Newly amended claim 14 now recites "one or more peptides selected from the group consisting of peptides of SEQ ID NOS: 3, 4, 7, 8, 9, 10, 11 and 12, and optionally one or two further peptides of SEQ ID NOS:1 and/or 2". It is unclear if first "one or more peptides" are to be the entire sequence of SEQ ID NOS:3, 4, 7, 8, 9, 10, 11 and 12, or subsequences of said SEQ ID NOS:3, 4, 7, 8, 9, 10, 11 and 12. Likewise, it is unclear if the "optionally one or two further peptides of SEQ ID NOS:1 and/or 2" are to be the entire sequence of SEQ ID NO:1 or 2 or subsequences of said SEQ ID NO:1 or 2.

Newly amended claim 16 now recites "comprising the peptides of SEQ ID NOS: 1, 2, 3, 4, 8, 9 and 10". It is unclear if the peptide(s) are to be the entire sequence of SEQ ID NO:1, 2, 3, 4, 8, 9 and 10, or subsequences of said SEQ ID NO:1, 2, 3, 4, 8, 9, and 10.

Claims 4-12, 17-18 and 28-30 depend from these claims, but do not clarify the indefiniteness.

Conclusion

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of

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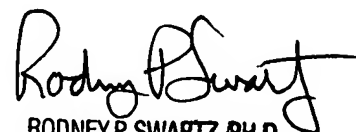
the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

October 10, 2005